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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,032	11/20/2003	Timothy A. Geiser	ACS 58145 (3166P)	2537

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,032	GEISER ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,18,24-34,37-39 and 44* is/are pending in the application.

4a) Of the above claim(s) *2,5-7 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8,9,18,24-34,38,39,44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/08 has been entered.

Claim Objections

2. Applicant is advised that should claims 2-4 be found allowable, claims 37-39 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1, 8, 9, 18, 25-32 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Wilson (USPN 6,019,778) and further in view of Vrba (USPN 6,254,609).**

5. Fischell discloses a catheter assembly (see entire document) comprising: a control handle (6); an inner catheter member including a distal mounting portion (defined by 71 and 23) adapted to have a medical device mounted thereon (40), a proximal portion (see 11 and 12, fig. 1) having a proximal end attached to the control handle, and a guide wire receiving member (63/65, Fig. 7) for receiving a guide wire (50), the guide wire receiving member being attached to the proximal portion of the inner catheter member (Col 7, lines 51-57 state that the metal joining tube (73) joins the guidewire lumen (65) to the shaft (72/12), the guide wire receiving member having a proximal end with an opening (66) and a distal end with an opening (19), a lumen (65) extending between these openings formed on the distal and proximal ends of the guide wire receiving member; and an outer catheter member (30) co-axially disposed over the inner catheter member and dimensioned for relative axial movement relative to each other, the outer catheter member having a distal portion (36) adapted to at least partially cover the medical device and a proximal end of the outer catheter attached to the control handle (Fig. 1), the outer catheter member being movable by the control handle to uncover the medical device, the outer catheter member including a proximal portion (32) having a lumen for receiving at least a portion of the inner catheter member and an intermediate portion (34) having a lumen through which the guide wire receiving member extends, wherein the proximal portion of the outer catheter member is attached to and extends into the lumen of the intermediate portion (see portion of Fig. 1 where arrow is 30 and note how 32 is connected to 34)) and the distal portion of the outer catheter

member is attached to the intermediate portion. The proximal end of the guidewire receiving member, which does not extend through the lumen of the distal mounting portion, is slidably disposed within the lumen of the intermediate portion of the outer catheter member. The distal mounting portion of the inner catheter member has a lumen (formed by (71) and (23)) and a portion of the guide wire member extends through the lumen (see Fig. 1 and 7). The guidewire member is secured to the wall (71) of the lumen at location (73). The lumen of the intermediate portion has a proximal opening (62) and the guidewire member extends into the opening.

6. Fischell does not disclose the sheath portion being made from a nylon-coated polyimide.

7. Wilson discloses a sheath with an outer layer that is preferably nylon bonded to an inner layer that is preferably PTFE. (Col 6, line 33-39)

8. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sheath with a nylon outer layer and a PTFE inner layer since Wilson discloses that this is a preferable combination of materials for a sheath in a stent deliver device. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

9. Fischell in view of Wilson does not disclose that the inner layer is a polyimide but rather a PTFE.

10. Vrba discloses that it is well known to substitute polyimide for PTFE as an inner layer of a sheath that is in direct contact with a stent.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate polyimide into the inner layer of the sheath in place of PTFE. Fischell in view of Wilson discloses the claimed invention except for PTFE instead of polyimide. Vrba

shows that polyimide is an equivalent material known in the art. Therefore, because the two materials were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the polyimide for PTFE.

12. Claims 3, 4, 24, 33, 34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Wilson in view of Vrba and further in view of Cummings (USPN 6,736,839).

13. Fischell modified by Wilson and Vrba discloses the invention substantially as claimed as stated above except for the proximal portion being formed from a hypotube.

14. Cummings discloses a stent delivery device incorporating a sheath where in a hypotube is the proximal portion of the sheath or outer member (Col 3, line 60-67). The hypotube incorporates a flush lumen for flushing fluid.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hypotube into the proximal portion of the device disclosed by Fischell modified by Wilson and Vrba since it is well known in the art to use hypotubes for increased strength and pushability. It is well known in the art that hypotubes are made form stainless steel or nickel-titanium. With the incorporation of a hypotube, the proximal portion will inherently be less flexible than the intermediate portion.

Response to Arguments

Applicant's arguments filed 02/14/08 have been fully considered but they are not persuasive. Applicant states that Wilson discloses a wire reinforcing layer in between recited outer layer and inner layer. Applicant goes on to say that because of this wire layer, the outer

Nylon layer is not bonded to the inner layer. However, examiner strongly disagrees. With reference to Figure 6, the reinforcing wire is an open braid having space in between the wire. It is at the location of these open spaces, in between the wire, that the layers are bonded to each other. It is well known in the art that reinforcing coils and braids are designed with various pitches depending on the amount of stiffness or flexibility required. It is therefore not unforeseen that the braid of Wilson would have some open space through which the two layers would be bonded.

It is unclear to the examiner how the existence of a reinforcing coil has any effect on the interchangeability of PTFE with polyimide as applicant suggests. Vrba discloses an inner layer of a sheath that contacts a stent prior to delivery just as WIlson does. Vrba further discloses that the inner sheath be less creep resistant and provides a list of preferable materials to meet these needs. Those preferable materials are either PTFE or polyimide. The fact that Wilson's sheath has an additional element of a reinforcing braid has no bearing on substituting one known material for another for the inner layer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Robin O. Evans/
TQAS, Technology Center, 3700